

## REMARKS

### I. INTRODUCTION

The final Office Action mailed on September 15, 2006 has been carefully studied and, in view of the following representations, reconsideration and allowance of this application are most respectfully requested.

### II. REJECTIONS UNDER 35 U.S.C. § 102(b)

Claims 51-64 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Doyle et al. (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10/18/00). Applicants respectfully submit that these rejections should be withdrawn for at least the following reasons.

To anticipate a claim, a reference must disclose each and every element of the claimed invention. *Verdergaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987). Applicants respectfully submit that Doyle et al. does not disclose or suggest each and every element of the pending claims.

In contrast to the disclosure of Doyle et al., the method of the presently claimed invention, as currently recited in pending claims 51-56 and 63, includes the claim recitation of “wherein the mammal is asymptomatic to lung damage or wherein the clinical diagnosis of lung damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures.” Similarly, the method of the presently claimed invention, as currently recited in pending claims 57-62 and 64 includes the claim recitation of “wherein the mammal is asymptomatic to alveolo-capillary membrane damage or wherein the clinical diagnosis of alveolo-capillary membrane damage in the mammal cannot otherwise be

confirmed without the aid of one or more invasive procedures.” Neither such mammal group is expressly or inherently disclosed in Doyle et al.

Although the Office Action asserts that “[n]ormal and the other tested patients [in Doyle et al.] are asymptomatic to lung damage, alveolo-capillary membrane damage or at a time period wherein the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures[, and that t]hese patient populations clearly meet the preamble and encompass testing normal or other control individuals not placable in any particular disease group” (Office Action mailed on September 15, 2006, page 3), Applicants respectfully disagree. That is, Doyle et al. does not disclose or suggest that the members of the control group (*i.e.*, normal individuals) or OD group (*i.e.*, ventilated patients with no evidence of cardiorespiratory disease) are necessarily “asymptomatic to” lung damage or alveolo-capillary membrane damage, or that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the mammal “cannot otherwise be confirmed without the aid of one or more invasive procedures.”

In that regard, Applicants respectfully point out that “[t]o establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted) (emphasis added); *see also In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (CAFC reversed obviousness rejection because inherency was based on “optimal” conditions, and the

means for achieving such "optimal" conditions were not explicitly or implicitly disclosed in prior art); M.P.E.P. § 2112, IV. Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic *may* occur in the prior art does not establish the inherency of that result or characteristic.

Thus, for at least the preceding reasons it is respectfully submitted that the rejections under 35 U.S.C. § 102(b) should be withdrawn.

### III. REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 51-64 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Honda (Japanese Journal of Thoracic Diseases, 34 Suppl Abstract only, December 1996; reference A11 on PTOL-1449 of 6/6/00) in view of Doyle et al. and Abe et al. (Japanese Journal of Thoracic Diseases, 33(11):1219, Abstract only, November 1995; reference A10 on PTOL-1449 of 6/6/00). Applicants respectfully submit that these rejections should be withdrawn for at least the following reasons.

In order for a claim to be rejected for obviousness under 35 U.S.C. § 103(a), not only must the prior art teach or suggest each element of the claim, but the prior art must also suggest combining the elements in the manner contemplated by the claim. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F. 2d 931, 934 (Fed. Cir. 1990), *cert. denied* 111 S.Ct. 296 (1990); *In re Bond*, 910 F. 2d 831, 834 (Fed. Cir. 1990). The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *See* M.P.E.P. §2142. To establish a *prima facie* case of obviousness, the Examiner must show, *inter alia*, that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references and that,

when so modified or combined, the prior art teaches or suggests all of the claim limitations. *See* M.P.E.P. §2143. Applicants respectfully submit that a *prima facie* case of obviousness has not been established in regard to the pending claims.

As described above in regard to the anticipation rejections, Doyle et al. does not disclose or suggest the claim recitation of “wherein the mammal is asymptomatic to lung damage or wherein the clinical diagnosis of lung damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures,” as currently recited in claims 51-56 and 63. Likewise, Doyle et al. does not disclose or suggest the claim recitation of “wherein the mammal is asymptomatic to alveolo-capillary membrane damage or wherein the clinical diagnosis of alveolo-capillary membrane damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures,” as currently recited in claims 57-62 and 64.

Neither Honda nor Abe et al. cure the shortcomings of Doyle et al. According to Honda, “the concentrations of SP-D and SP-A were measured in sera of patients with idiopathic interstitial pneumonia (IIP),” and then compared to “samples from healthy volunteers.” Honda, lines 3-6. In Abe et al., the serum SP-A levels in patients with idiopathic interstitial pneumonia, pulmonary alveolar proteinosis, and collagen disease with interstitial pneumonia were compared to those in healthy volunteers. *See* Abe et al., lines 7-9. However, neither Honda nor Abe et al. disclose or suggest that the healthy volunteers are necessarily “asymptomatic to” lung damage or alveolo-capillary membrane damage, or that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the mammal “cannot otherwise be confirmed without the aid of one or more invasive procedures.” The only meaningful characteristic of the “healthy volunteers” in Honda is that they do not have

idiopathic interstitial pneumonia, while the only meaningful characteristic of the "healthy volunteers" in Abe et al. is that they do not have idiopathic interstitial pneumonia, pulmonary alveolar proteinosis, or collagen disease with interstitial pneumonia. Furthermore, Honda and Abe et al. only disclose measurements of SP-D and SP-A, and SP-A, respectively.

Thus, for at least the preceding reasons it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) should be withdrawn.

IV. CONCLUSION

In light of the foregoing, Applicants respectfully submit that all pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,  
KENYON & KENYON LLP

Dated: March 15, 2007

By:   
Kevin T. Godlewski  
Reg. No. 47,598

KENYON & KENYON LLP  
One Broadway  
New York, NY 10004  
Telephone: (212) 425-7200  
Facsimile: (212) 425-5288